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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,454	04/16/2004	Gregory J. LaRosa	10448-215011 / MPI98-129C	1309
8933	7590	05/22/2006	EXAMINER	
DUANE MORRIS, LLP IP DEPARTMENT 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103-4196			CROWDER, CHUN	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/826,454

Applicant(s)

LAROSA ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.
2. Claims 1-43 are pending

***Election/Restriction***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10 and 37-42, drawn to an antibody or antigen binding fragment which binds to a CC-chemokine receptor 2 (CCR2) and a composition comprising an antibody or antigen-binding fragment thereof, classified in Class 530, subclass 387.1; Class 424, subclass 133.1.
  - II. Claim 11, drawn to a test kit comprising at least one antibody or antigen-binding fragment thereof which binds to CCR2, and one or more ancillary reagents, classified in Class 435, subclass 810.
  - III. Claims 12-20, 25, 26, 33-36, and 43, drawn to a method of inhibiting the interaction of a cell bearing mammalian CCR2 with a ligand, classified in Class 424, subclass 130.1.
  - IV. Claims 21-24, drawn to a method of detecting a mammalian CCR2 comprising contacting a sample with an antibody or antigen-binding fragment which binds to a mammalian CCR2, classified in Class 435, subclass 355.
  - V. Claims 27-32, drawn to a method of detecting or identifying an agent which binds a mammalian CCR2, classified in Class 435, subclass 7.1.

4. Inventions I and II are related as products, which share an alleged common utility of detecting the presence of a mammalian CCR2 but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility.

In this case, the antibody can be used for affinity purification in addition to be included in a test kit for detecting the presence of a mammalian CCR2.

It is noted that Group II encompass a test kit comprising at least one antibody or antigen-binding fragment thereof and one or more ancillary reagents. It is not clear what other antibodies and ancillary reagents are encompassed in the test kit, in addition to antibody or antigen-binding fragment that binds a mammalian CCR2. For restriction purpose, claim 11 is grouped separate from Group I.

5. Inventions (I and III-V) and (II and IV/V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case, the antibody can be used in affinity purification in addition to method of detecting the mammalian CCR2.

6. Inventions III-Vare different methods. The methods differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### ***Species Election***

8. Applicant is further required under 35 U.S.C. 121 to (1) elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claims is finally held to be allowable and (2) list all claims readable thereon including those subsequently added.

9. If either one of Groups I-V is elected, applicant is further required to elect one specific antibody or antigen-binding fragment thereof that inhibits binding of one specific ligand to the receptor (e.g. MCP-1 as recited in claim 5).

These species are distinct because their structures, physicochemical properties and mode of action are different. Further, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

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Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merit to which the claims would be restricted if no generic claim is finally held to be allowable.

10. If Groups III is elected, applicant is further required to elect one specific method of inhibiting one specific cell type (e.g. CD8<sup>+</sup> cells as recited in claims 14 and 19).

These species are distinct because methods of inhibiting different cell types differ with respect to one or more of ingredients, method steps and/or endpoints. Furthermore, the examination of the different ingredients, method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merit to which the claims would be restricted if no generic claim is finally held to be allowable.

11. In addition, if Group III is elected, applicant is further required to elect one specific method of treating one specific disorder (e.g. HIV as recited in claims 22 and 33).

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merit to which the claims would be restricted if no generic claim is finally held to be allowable.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.

Patent Examiner

May 1, 2006

*PHILLIP GAMBEL*  
PHILLIP GAMBEL, PH.D. JD  
PRIMARY EXAMINER  
*TZ 1600*  
*5/10/06*